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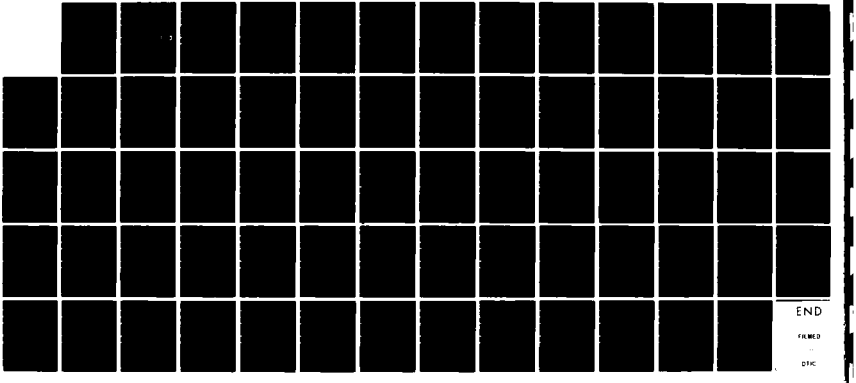

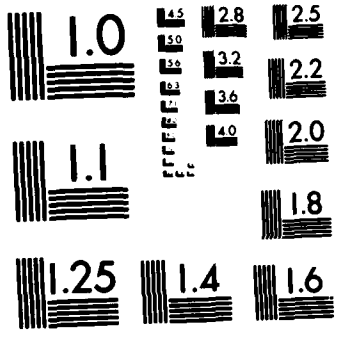


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| | |
|---|---|
| 1. REPORT NUMBER: AFIT/CI/NR 84-53T | 2. GOVT ACCESSION NO. |
| 3. RECIPIENT'S CATALOG NUMBER | |
| 4. TITLE (and Subtitle): Assessing Practitioner Attitudes Towards the Role of Pharmacists in Therapeutic Alternate and Pharmaceutical Alternate Substitution | 5. TYPE OF REPORT & PERIOD COVERED: THESIS/DISSERTATION |
| | 6. PERFORMING ORG. REPORT NUMBER |
| 7. AUTHOR(s): Roger D. Wetherington | 8. CONTRACT OR GRANT NUMBER(s) |
| 9. PERFORMING ORGANIZATION NAME AND ADDRESS: AFIT STUDENT AT: The University of North Carolina Chapel Hill | 10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS |
| 11. CONTROLLING OFFICE NAME AND ADDRESS: AFIT/NR WPAFB OH 45433 | 12. REPORT DATE: June 1984 |
| | 13. NUMBER OF PAGES: 64 |
| 14. MONITORING AGENCY NAME & ADDRESS(if different from Controlling Office) | 15. SECURITY CLASS. (of this report): UNCLASS |
| | 15a. DECLASSIFICATION/DOWNGRADING SCHEDULE |

16. DISTRIBUTION STATEMENT (of this Report)

APPROVED FOR PUBLIC RELEASE; DISTRIBUTION UNLIMITED

DTIC ELECTE SEP 13 1984 S D B

17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)

18. SUPPLEMENTARY NOTES

APPROVED FOR PUBLIC RELEASE: IAW AFR 190-1

5 Sept 84

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Dean for Research and
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AFIT, Wright-Patterson AFB OH

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## INTRODUCTION

Throughout the 1970's generic substitution of drug products was a controversial issue with different groups holding varying points of view. During this period state governments removed their drug product antisubstitution laws. Today every state allows some form of generic drug substitution. Satisfied with what was accomplished with generic drugs, pharmacy leaders are looking to further extend pharmacy's authority by suggesting that pharmacists be allowed to substitute therapeutic and/or pharmaceutical alternate drug products on prescription orders.

Therapeutic Alternates are drug products containing different therapeutic moieties but which are of the same pharmacological class and/or therapeutic class that can be expected to have similar therapeutic effects when administered to patients in therapeutically equivalent doses. Pharmaceutical Alternates are drug products which contain the same therapeutic moiety and strength but differ in the salt, ester or dosage form, and are administered by the same route[6].

These forms of substitution evoke an even greater disparity of opinion and controversy between pharmacists, physicians, and industry representatives than did generic

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RESEARCH TITLE: Assessing Practitioner Attitudes Towards the Role of Pharmacists in Therapeutic Alternate and Pharmaceutical Alternate Substitution

AUTHOR: Roger D. Wetherington

RESEARCH ASSESSMENT QUESTIONS:

1. Did this research contribute to a current Air Force project?

( ) a. YES ( ) b. NO

2. Do you believe this research topic is significant enough that it would have been researched (or contracted) by your organization or another agency if AFIT had not?

( ) a. YES ( ) b. NO

3. The benefits of AFIT research can often be expressed by the equivalent value that your agency achieved/received by virtue of AFIT performing the research. Can you estimate what this research would have cost if it had been accomplished under contract or if it had been done in-house in terms of manpower and/or dollars?

( ) a. MAN-YEARS _____ ( ) b. $_____

4. Often it is not possible to attach equivalent dollar values to research, although the results of the research may, in fact, be important. Whether or not you were able to establish an equivalent value for this research (3. above), what is your estimate of its significance?

( ) a. HIGHLY SIGNIFICANT ( ) b. SIGNIFICANT ( ) c. SLIGHTLY SIGNIFICANT ( ) d. OF NO SIGNIFICANCE

5. AFIT welcomes any further comments you may have on the above questions, or any additional details concerning the current application, future potential, or other value of this research. Please use the bottom part of this questionnaire for your statement(s).

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STATEMENT(s):

# ASSESSING PRACTITIONER ATTITUDES TOWARDS THE ROLE OF PHARMACISTS IN THERAPEUTIC ALTERNATE AND PHARMACEUTICAL ALTERNATE SUBSTITUTION

by

Roger D. Wetherington

A Report submitted to the faculty of The University of North Carolina at Chapel Hill in partial fulfillment of the requirements of Master of Science in the School of Pharmacy.

Chapel Hill

June 29, 1984

Approved by:

Adviser

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substitution. Whether or not therapeutic alternate substitution will be as politically successful as was generic substitution is difficult to forecast. What is certain at this point is that these forms of substitution contain many more controversial areas than generic substitution. Without question, legalization of therapeutic alternate substitution and pharmaceutical alternate substitution would have significant economic and social consequences for everyone involved.

The impetus for allowing pharmacists to therapeutically substitute one drug for another appears to originate from two sources. First, and of greatest importance, are the hospital cost containment pressures resulting from proposed changes in federal and state drug reimbursement policies. Of particular relevance are the changes relating to reimbursement for ancillary services. These services will no longer be reimbursed on a cost based system, but under some form of prospective payment plan. This method of reimbursement will cause administrators to carefully monitor costs throughout their hospitals. Drug inventory costs will be an area that will receive increased managerial attention. The number of new drugs has increased. Because of the high costs involved in moving these drugs to market, they are expensive. Some believe: 1) that many of these drugs have similar or identical pharmacological properties to existing products and often represent only therapeutic duplications, and 2) that maintaining inventories of these drugs only

serves to increase inventory costs without improving patient care. Hospital administrators, through Pharmacy and Therapeutics Committees, see controlling inventory through formulary management as a means of limiting and/or reducing expenditures. It is assumed by some that drug costs can be significantly lowered if a hospital approves one product as the drug of choice for a therapeutic category, or if it allows automatic substitution of drug products that pharmacists and physicians believe are therapeutic equivalents.

The second source of support seems to be coming from some leaders within the pharmacy profession. In addition to recognizing that therapeutic substitution is a means of reducing inventory costs for hospital and community pharmacists, they believe, given the current training pharmacists receive, that therapeutic substitution may well be a logical extension of the pharmacist's role in health care.

What is lacking at this point, however, is information on how pharmacists and physicians feel about this issue and to what extent pharmacists feel qualified to undertake this new and important role. It remains to be seen if society, after considering all the issues involved with therapeutic substitution, will allow pharmacists to therapeutically substitute drugs.

## LITERATURE REVIEW

The literature on therapeutic substitution is primarily subjective, consisting principally of arguments for or against therapeutic substitution or reporting on how it works. Three articles[1,3,4] present objective evaluations of some aspect of the issue. Doering[1] et al. examined physician consent and statutory regulations relating to therapeutic substitution and found that some states had formally addressed the issue of therapeutic substitution. Oregon failed to pass a resolution introduced in 1982 that would have legalized therapeutic substitution and in doing so may be the only state in which therapeutic substitution is officially illegal. Washington passed a law making therapeutic substitution legal under certain restrictions that may effectively preclude its widescale adoption[2].

In other states, in the absence of legal authority, Doering found some hospitals have adopted policies and procedures allowing therapeutic substitution for products deemed therapeutically equivalent by their Pharmacy and Therapeutics Committees. In these hospitals physician consent may be obtained in one of two ways. First, the

physician may indirectly consent to therapeutic substitution when he agrees to abide by the regulations and bylaws of the hospital which usually include adherence to a drug formulary. The second form of consent, concurrent consent, is obtained by having the physician check or sign a statement on the prescription giving consent for substitution.

Doering[3] et al. also surveyed state regulatory agencies to determine their views on hospital policies towards therapeutic substitution. Questionnaires were sent to the pharmacy board secretaries in each state and the District of Columbia. Of the fifty-one jurisdictions surveyed, thirty-four answered all of the questions, thirteen answered some, and four did not respond. Seventeen agencies stated that if therapeutic substitution is in accordance with policies established by the Pharmacy and Therapeutics Committee, it is not subject to state or federal regulations. Two agencies gave qualified responses. Fifteen respondents stated that they would view therapeutic substitution as illegal. Seven agencies indicated that they would take enforcement action. Three agencies were uncertain what action would be taken, and twenty-three indicated no action would be taken. Thirty-nine agencies indicated that they had never taken action against a formulary system that allowed therapeutic substitution.

Current therapeutic substitution practices in short-term hospitals were also examined by Doering[4] et al. These

researchers found that approximately forty percent of hospitals have formulary systems that allow stocking of a single product representing a given therapeutic category. Approximately 31 percent of the hospitals responding reported that they allow therapeutic substitution without contacting the physician for permission. They also reported that therapeutic substitution was most prevalent in federal hospitals and that there were regional variations in the practice of therapeutic substitution. They were also able to identify hospital related factors that appear to be associated with therapeutic substitution and to identify reasons why hospitals did not engage in therapeutic substitution.

There is nothing in the literature which attempts to evaluate the influence of therapeutic substitution on drug therapy outcomes or cost saving, and nothing has been done to evaluate the attitudes of physicians towards therapeutic substitution. Only one study has been performed that investigated pharmacist's attitudes on therapeutic substitution. Drug Topics surveyed 625 pharmacists and found that 88 percent favor or strongly favor allowing pharmacist to therapeutically substitute[5]. They reported that pharmacists supported this role for the following reasons: it would eliminate unnecessary duplication and they are trained to do it. It is unclear as to whether or not the pharmacists answering this question were well informed on the legal and operational problems involved with

therapeutic substitution. Nor was it clear that the respondent knew the difference between therapeutic substitution and substitution of pharmaceutical alternates.

## OBJECTIVES

The primary objective of this study was to determine pharmacists and physicians attitudes towards therapeutic alternate substitution and pharmaceutical alternate substitution. In addition, the study identified factors which each group considered important in determining their position, e.g., the importance of patient cost savings, adequacy of pharmacist training for this role, physician willingness to accept pharmacists in this role, acceptance of therapeutic substitution in a hospital setting, and acceptance of therapeutic substitution in a community pharmacy setting. Each of the issues and factors were also examined for pharmaceutical alternate substitution. The data was analyzed by respondent characteristics for significant differences in attitudes to test the following hypotheses:

1. There is no difference in pharmacists' and physicians' attitudes towards the role of pharmacists in therapeutic alternate substitution or pharmaceutical alternate substitution.

2. There is no difference in the attitude of pharmacists' or physicians' towards the appropriateness of therapeutic alternate substitution and/or pharmaceutical alternate substitution in hospitals versus community pharmacies.

3. Physicians and pharmacists favor regulations permitting pharmacist substitution of therapeutic alternates and pharmaceutical alternates without restrictions.

4. There is no difference in pharmacists' attitudes towards their ability to make rational therapeutic alternate substitutions versus their ability to make rational pharmaceutical alternate substitutions.

5. Pharmacists with advanced degrees do not have a different attitude towards the role of pharmacists in therapeutic alternate and/or pharmaceutical alternate substitution than pharmacists with only an entry level degree.

6. Age is not a factor in determining physicians' or pharmacists' attitude towards therapeutic alternate substitution and/or pharmaceutical alternate substitution.

7. The physicians' specialty is not a determinant of his/her attitude toward pharmacists making therapeutic alternate and/or pharmaceutical alternate substitutions.

8. Where a pharmacist works is not a determinant of his/her attitude toward pharmacists making therapeutic alternate and/or pharmaceutical alternate subatitutions.

## METHODOLOGY

Data for this study was collected via a self-administered questionnaire distributed to a random national sample of 500 physicans and 500 pharmacists. The physician sample was selected according to the percentage of prescriptions written by each specialty until 80 per cent of total prescriptions was reached. The remainder of the physician sample was randomly selected from the unrepresented specialties. An American Medical Association data base was used for the sample source. The pharmacist sample was drawn from a National Association of Boards of Pharmacy data base. It was not possible to draw a sample of pharmacist by degree or primary place of employment, therefore, the sample was totally random and selected without any demographic restrictions.

There was one follow-up mailing and telephone calls to ten randomly selected pharmacists to determine significant differences between responders and nonresponders. The questionnaires were mailed using the University of North Carolina bulk mail permit. Business reply postage was included for the respondents return mailing.

The questionnaire was designed and developed using techniques recommended by Dillman[7]. The questionnaire was pretested with pharmacists and physicians in Chapel Hill, N.C. The results of the pretest were analyzed and necessary revisions completed prior to mailing to the national sample.

The questionnaire consisted of a series of attitudinal statements, a series of close-ended questions, demographic questions and space for the respondent to volunteer additional comments. The questionnaire was self-enclosed, so that the respondent had only to fold over the back cover on which the return address and postage were provided and staple or tape it closed to mail. The physician questionnaire contained 20 therapeutic alternate substitution Likert scale statements and 17 pharmaceutical alternate substitution Likert scale statements. There were 6 close-ended questions, identical for both therapeutic alternate substitution and pharmaceutical alternate substitution, that asked the respondent to choose 1 or more items from a menu, or to write in his/her own choice. The physician respondents were asked to provide demographic data on their age, sex, state in which practice, years in practice, medical specialty and type of practice, ie hospital, office, etc. A copy to the physician questionnaire is included as Appendix A. The pharmacist questionnaire contained 22 Likert scale statements concerning therapeutic alternate substitution and 19 Likert scale statements concerning pharmaceutical alternate

substitution. The identical set of close-ended questions as in the physician questionnaire were included. Pharmacist respondents were asked to provide demographic data on age, sex, years in practice, state in which practice, highest degree held and practice site, ie independent community pharmacy, hospital, etc. A copy of the pharmacist questionnaire is included as Appendix B. Both physician and pharmacist questionnaires included a page at the end for additional comments. The study data was analyzed using the computer facilities available to the School of Pharmacy at the University of North Carolina, Chapel Hill, NC.

## RESULTS

### Demographic Data

Fifty-nine questionnaires were returned by physicians for a response rate of 12 per cent, 104 questionnaires were returned by pharmacists for a response rate of 21 per cent. The low response rate may be attributed to the length of the questionnaire and the controversial and emotional nature of the issue of pharmacist selection of drug products.

Summary statistics on respondents' demographics are shown in Tables 1 & 2. The average age for physician respondents was 41.5 years. The average age of pharmacist respondents was 43.9 years. Twenty-one percent of physician respondents and 19.6 per cent of the pharmacists, respectively, were female. Physician respondents were distributed by specialty as follows: Family Practice--25%, Pediatrics--17%, Internal Medicine--17%, and other specialties--41%. Pharmacist distribution by primary place of employment was as follows: independent pharmacies--36%, small chains (<10 stores)--5%, large chains (>10 stores)--20%, hospitals--19%, government--5%, teaching--2%, other--13%. Pharmacist

distribution by degree was as follows: BSPh--75%, Graduate degree--13%, other--12%.

Summary Data: Attitudinal Statements

Summaries of the responses to the attitudinal statements for therapeutic alternate substitution and pharmaceutical alternate substitution are presented in Tables 3, 4, & 5. The respondents were asked to indicate their level of agreement by circling one of the following responses: Strongly Agree, Agree, No Opinion, Disagree, Strongly Disagree. Each response was assigned a point value ranging from 5 points for Strongly Agree to 1 point for Strongly Disagree. Mean responses, by profession, for each attitudinal statement were then calculated. These tables also show the results of T-test analysis for significant differences in the mean responses between the professions.

The differences between the statement means were significant for all the statements regarding therapeutic alternate substitution in hospitals or community pharmacies. However, the only statements for which the differences were significant when these statements were asked regarding pharmaceutical alternate substitution were the statements concerning making substitutions in hospitals and community pharmacies without prior physician consent.

Attitudinal Data: Physicians

The physician responses were analyzed according to age, sex, and specialty. When analyzed for attitude towards therapeutic alternate substitution by age, the only

significant difference was on the issue of Medicine/Pharmacy relationship. The older group of physician respondents more highly agreed that this issue could weaken the relationship between the professions. Analysis of the pharmaceutical alternate substitution questions by age revealed significant differences on the contribution of pharmaceutical alternate substitution toward lowering prescription prices and on the question of acceptability if the patient agreed to the change. A younger group of physicians had a higher level of agreement on each of these questions.

An analysis of the physician responses according to sex revealed significant differences only for the effect of therapeutic alternate substitution and pharmaceutical alternate substitution on lowering prescription prices. Women respondents had a higher level of agreement for both therapeutic alternate substitution and pharmaceutical alternate substitution. The only question for which there was a significant difference when analyzed by medical specialty was between pediatricians and internal medicine specialists on the question of therapeutic duplications within drug classes, with pediatricians having the higher level of agreement.

A further analysis of physician responses showed significant differences in attitude level for the following comparisons: (1) that approval was higher for using protocols for therapeutic alternate substitution in hospitals than in community pharmacies, (2) that approval

for pharmaceutical alternate substitution is higher in hospitals than for therapeutic alternate substitution when the pharmacist informs the physician of the change, (3) that approval of pharmaceutical alternate substitution is higher than approval of therapeutic alternate substitution in hospitals when done without prior physician consent, (4) that approval of pharmaceutical alternate substitution is higher in hospitals than in community pharmacies when the pharmacist informs the physician of the change, (5) that approval for pharmaceutical alternate substitution is higher than for therapeutic alternate substitution in community pharmacies when the pharmacist must inform the physician of the change, and (6) that approval of pharmaceutical alternate substitution is higher than therapeutic alternate substitution in community pharmacies when done without prior physician consent.

Attitudinal Data: Pharmacists

Pharmacist responses were analyzed by age, sex, highest degree held, and principle place of employment. The analysis of the therapeutic alternate substitution statements according to age revealed that younger pharmacists had a significantly higher level of agreement on the statements concerning (1) the probable effect of therapeutic alternate substitution on increasing patient compliance, (2) acceptablility of the role of therapeutic alternate substitution if the pharmacist has completed appropriate continuing education courses, and (3)

acceptability of the role of therapeutic alternate substitution in practice sites where the pharmacist has access to patient medical records. Significant differences for the pharmaceutical alternate substitution questions, when analyzed according to age, were found on 8 questions. Younger respondents had significantly higher levels of agreement with the statements concerning (1) the appropriateness of pharmaceutical alternate substitution without prior physician consent in both hospitals and community pharmacies, (2) the favorable effect that pharmaceutical alternate substitution could have on increasing patient compliance, and (3) the acceptability of pharmaceutical alternate substitution in sites where the pharmacist has access to the patients medical record. The older respondents had significantly higher levels of agreement on the statements (1) where, in community pharmacies, the pharmacist must inform the physician of the change, (2) that pharmaceutical alternate substitution may increase the incidence of inappropriate drug therapy in both hospitals and community pharmacies, and (3) that pharmaceutical alternate substitution may increase the legal liability for pharmacists.

An analysis of the pharmacist data by sex revealed that males had higher levels of agreement for the therapeutic alternate substitution statements concerning (1) the appropriateness of therapeutic alternate substitution in hospitals or community pharmacies without prior physician

consent, (2) conflict of interest if physician dispenses, (3) qualification of community and hospital pharmacists to make rational therapeutic alternate substitution decisions. With regard to pharmaceutical alternate substitution, females had significantly higher levels of agreement on the statements concerning (1) the effect of pharmaceutical alternate substitution on increasing the the incidence of inappropriate drug therapy in hospitals and (2) the acceptability of pharmaceutical alternate substitution in practice sites where the pharmacist has access to patient medical records.

There were also significant attitude differences between pharmacists in independent community pharmacies and pharmacists in the "other" category for the statements relating to the knowledge level of community and hospital pharmacists being sufficient to make rational therapeutic alternate substitution decisions. No significant differences were found on any questions when the data was analyzed by highest degree held.

Additional analysis of the pharmacist responses showed further significant differences as follows: (1) the level of agreement with using protocols for therapeutic alternate substitution is higher in hospitals than in community pharmacies, (2) that, in hospitals, using protocols is more appropriate for therapeutic alternate substitution than for pharmaceutical alternate substitution, (3) that, in hospitals, pharmaceutical alternate substitution is more

appropriate than therapeutic alternate substitution when done without prior physician consent, (4) that pharmaceutical alternate substitution without prior physician consent is more appropriate in hospitals than in community pharmacies, (5) that the level of agreement is higher for using protocols for therapeutic alternate substitution than for pharmaceutical alternate substitution in community pharmacies, (6) that, in community pharmacies, pharmaceutical alternate substitution is more appropriate than therapeutic alternate substitution when done without prior physician consent, and (7) the level of agreement is higher that their training/experience has provided the skills necessary to perform pharmaceutical alternate substitution than to perform therapeutic alternate substitution.

Close-ended Questions

The questionnaire contained an identical series of close-ended questions for both the therapeutic alternate substitution and pharmaceutical alternate substitution sections. The purposes of these questions were to: (1) identify whether the respondent favored regulations allowing therapeutic alternate substitution and pharmaceutical alternate substitution, (2) acceptable conditions under which therapeutic alternate substitution/pharmaceutical alternate substitution might be implemented, (3) the best reasons for allowing therapeutic/pharmaceutical alternate substitution, (4) the best reasons for not allowing

therapeutic/pharmaceutical alternate substitution, (5) information a pharmacist needs in order to select a therapeutic/pharmaceutical alternate and (6) identify information the respondent feels he/she needs in order to arrive at a decision whether or not to support therapeutic/pharmaceutical alternate substitution as a pharmacist function. For all of these questions except the question asking if the respondent favored regulations allowing therapeutic/pharmaceutical alternate substitution, the respondent was allowed to give two or more responses.

Respondents were first asked if they presently were in favor of regulations allowing therapeutic/pharmaceutical alternate substitution. The results of this question are contained in Table 6. As can be seen, with regard to therapeutic alternate substitution, physicians are almost evenly divided between allowing regulations that would allow therapeutic alternate substitution if there were restrictions and not passing regulations that allow therapeutic alternate substitution in any form. No physician respondent was in favor of regulations allowing therapeutic alternate substitution without restriction. In contrast, with regard to pharmaceutical alternate substitution, 55 per cent of the physician respondents were in favor of regulations that contain some restrictions and 7 per cent were in favor of regulations, even if not containing restrictions. Pharmacists were much more strongly in favor of regulations allowing both therapeutic

alternate substitution and pharmaceutical alternate substitution than physicians. With regard to therapeutic alternate substitution, 81 per cent of pharmacist respondents were in favor of either regulations with restrictions (67%) or regulations even without restrictions (14%). Pharmacist support of regulations allowing pharmaceutical alternate substitution was even stronger, with 94 per cent of respondents either in favor of regulations with restrictions (46%) or in favor of regulations even if without restrictions (48%).

If respondents answered that they were in favor of regulations that contained restrictions, they were then asked to identify two conditions under which they would approve of therapeutic alternate substitution and pharmaceutical alternate substitution. Table 7 contains the data from this question. The ranking of conditions by pharmacists and physicians was the same for both therapeutic alternate substitution and pharmaceutical alternate substitution. Use of protocols was the condition most frequently chosen. That therapeutic alternate substitution and pharmaceutical alternate substitution might save the patient money was the least frequently chosen condition seems to indicate that both groups feel there are more isues more important than cost savings to be considered in implementing these programs.

Respondents who answered that they favored regulations with restrictions or that they favored regulations (without

restrictions) were then asked to select the two best reasons for passing regulations allowing pharmacists to select therapeutic alternate substitution and pharmaceutical alternate substitution. Data for this question are contained in Table 8. With regard to therapeutic alternate substitution, the most frequent response for both groups was that therapeutic alternate substitution would result in lower prescription prices to consumers. The second most frequent selection of physicians was that therapeutic alternate substitution would promote more rational drug therapy. For pharmacists, the second most frequent response was that pharmacists' training and expertise would be more fully utilized. Physicians, again, chose the probable lowering of prescription prices as the best reason for implementing pharmaceutical alternate substitution. Physicians' second choice was most often that the pharmacist is knowledgeable enough to select pharmaceutical alternate substitution. Pharmacists differed from physicians in choice of best reasons for allowing pharmaceutical alternate substitution. Pharmacists' most frequent response was that their training and expertise would be more fully utilized were they allowed to select pharmaceutical alternate substitution, and that the probable lowering of prescription costs was the second best reason for allowing pharmaceutical alternate substitution.

Data regarding the question of what information is needed before a pharmacist selects a therapeutic alternate

or pharmaceutical alternate is presented in Table 9. Regarding therapeutic alternate substitution, physician responses are essentially the same for all choices, with therapeutic equivalence data and cost data being rated exactly equal. Pharmacists' responses were more varied, with therapeutic equivalence data being the most frequent response and patient diagnosis being second. Cost data was the fourth most frequent response for pharmacists. With regard to pharmaceutical alternate substitution, physicians rated bioequivalence data and cost data equall. Pharmacists rated bioequivalence data as clearly the imformation they felt most important and cost data as the second most important.

As shown in Table 10, respondents from both groups who answered that they were not in favor of regulations allowing therapeutic alternate substitution or pharmaceutical alternate substitution rated the physicians' greater familiarity with their patients as being the best reason for not allowing therapeutic/pharmaceutical alternate substitution. Both groups also rated the physician as the only one qualified to select alternates as the least frequent response.

Non-Responder Data

In an attempt to characterize non-respondents, follow-up calls were made. Ten pharmacists were selected at random and contacted. Eight of the ten were male, the average age of the ten was 52 years, and all ten had earned the Bachelor

of Science as the highest pharmacy degree. The non-respondents were asked if they currently favored regulations allowing therapeutic alternate substitution or pharmaceutical alternate substitution. All of the respondents indicated that they favored regulations with restrictions for therapeutic alternate substitution. Nine of the respondents indicated that they favored regulations with restrictions for pharmaceutical alternate substitution, and one respondent indicated favor of regulations without restrictions.

## DISCUSSION

The significant differences that exist between physicians and pharmacists in their attitudes towards both therapeutic alternate substitution and pharmaceutical alternate substitution leads to the rejection of Hypothesis #1. Pharmacists view therapeutic alternate substitution and pharmaceutical alternate substitution much more favorably than do physicians. Physicians do not seem to make a strong distinction between therapeutic alternate substitution and pharmaceutical alternate substitution. Although the overall physician attitude towards pharmaceutical alternate substitution is higher than for therapeutic alternate substitution, the difference is not great enough to indicate significant physician support for pharmaceutical alternate substitution. Many physicians included comments to the effect that pharmacists knowledge of salts and esters of drugs was superior to theirs. Pharmacist respondents attitudes towards pharmaceutical alternate substitution is also higher than for therapeutic alternate substitution, and many pharmacists comments indicated a belief that

pharmaceutical alternate substitution is an appropriate pharmacist function.

Based on analysis of responses to the hospital and community pharmacy questions relation to therapeutic alternate substitution and pharmaceutical alternate substitution, it appears that there are significant differences towards the appropriateness of either therapeutic alternate substitution or pharmaceutical alternate substitution in either practice setting. Therefore, Hypothesis #2 is not accepted.

The results presented in Table 6 show that the majority of each group that favor regulations permitting therapeutic alternate substitution and pharmaceutical alternate substitution do prefer some restrictions be placed on these functions, leading to the rejection of Hypothesis #3 as it concerned therapeutic alternate substitution. There were no physicians that indicated they would favor regulations allowing therapeutic alternate substitution without restrictions and only 14 per cent of pharmacists chose this option. With regard to pharmaceutical alternate substitution, 7 per cent of physicians indicated they would favor pharmaceutical alternate substitution regulations without restrictions, while 48 per cent of pharmacists chose this option. Hypothesis #3, with regard to pharmaceutical alternate substitution, is rejected for physicians and not rejected for pharmacists.

The analysis of responses to the question asking if training/experience has provided pharmacists the skills to perform therapeutic alternate substitution and/or pharmaceutical alternate substitution causes Hypothesis #4 to be rejected. Pharmacists indicated a much greater level of agreement that they are prepared to perform pharmaceutical alternate substitution over therapeutic alternate substitution. Responses to other statements and questions, as well as many written comments, serve to reinforce this conclusion. Hypotheses 5-8 are also rejected. Age, degree, physician specialty, or pharmacist place of employment do not seem to be factors which influence a respondents attitudes. Younger physician respondents, however, generally had more favorable responses than the older respondents. Although the differences between physician age groups were not great, that there is a difference may be attributable to the fact that an increasing number of pharmacists are being trained with and participating in the training of younger physicians. This was not generally the case before the widespread inclusion of clinical pharmacy training by pharmacy schools.

Some of the pharmacy literature strongly advocates both therapeutic alternate substitution and pharmaceutical alternate substitution as appropriate functions for pharmacists. The results of this survey indicate that our sample of pharmacists generally support this viewpoint. However, the low level of agreement with the statements

concerning appropriateness of therapeutic alternate substitution and pharmaceutical alternate substitution without prior physician consent indicates that this sample of pharmacists are not ready to assume the independent performance of these function. The results do show that the level of support by both physicians and pharmacists is much higher in situations where some form of feedback to physicians is provided for, or where the physician has some input into the selection process (either through protocols, Pharmacy & Therapeutics Committee approval, or when the pharmacist must inform the physician of the change).

Responses of physicians' and pharmacists' were more favorable toward both therapeutic alternate substitution and pharmaceutical alternate substitution in hospitals than in community pharmacies. This is probably due to the greater ease of communication and generally closer interaction between physicians and pharmacists in the hospital setting. In the community pharmacy setting, arranging protocols with each physician or having to inform each physician every time a change is made would impose a tremendous time burden on both physicians and pharmacists.

Responses to the question asking whether the respondent is in favor of regulations allowing therapeutic alternate substitution shows that physicians are almost equally divided between allowing regulations that place some restriction on the practice and on making no changes to the present regulations. The physician responses to the same

question with regard to pharmaceutical alternate substitution shows that physicians are much less opposed to pharmaceutical alternate substitution, but still strongly favor regulations that would place some restrictions on the practice. That physician responses were relatively high to approving therapeutic alternate substitution and pharmaceutical alternate substitution if some form of restrictions are in place may indicate that the profession is not as adamantly opposed to the concept as some of the literature indicates.

Pharmacist responses to this question are similiar to physician responses in that few pharmacists indicated that therapeutic alternate substitution should be allowed without some restrictions. Pharmacists are much more in favor of pharmaceutical alternate substitution without restrictions, however, approximately as many would favor regulations that place some restrictions as would favor regulations without restrictions. This further supports the finding that pharmacists do not strongly support the independent performance of these functions.

The following factors may be considered possible study limitations. Because of the relatively low response rate, representative samples of the study populations may not have been obtained. Although the survey was long, it is still quite likely that some relevant and important issues were not included. Also, as with any complex issue, it is possible that semantics may have led to misunderstandings as

to what was being asked and, consequently, the responses may not have reflected the respondents true attitudes.

## CONCLUSIONS AND RECOMMENDATIONS

Although physicians are aware of the differences between therapeutic alternate and pharmaceutical alternate substitution, they do not approve one over the other as a pharmacist function. However, physicians may not be as strongly opposed to these issues as some of the literature indicates. Physicians seem to be more in favor of permitting pharmacists to select pharmaceutical alternates than to permit selection of therapeutic alternates. Several comments from physicans indicate that they do not seem to be aware of the training pharmacists receive that provides them the knowledge and skill necessary to perform therapeutic alternate substitution and pharmaceutical alternate substitution. While pharmacists generally are in favor of both therapeutic alternate substitution and pharmaceutical alternate substitution, their support of pharmaceutical alternate substitution is much stronger than their support of therapeutic alternate substitution. Pharmacists do not seem to favor the position granting independent authority to select therapeutic alternates or pharmaceutical alternates.

Consequently, pharmacy policy makers should concentrate their efforts at this time on establishing pharmaceutical alternate substitution as a role for pharmacists. Programs should be developed to increase physician awareness of and appreciation for pharmacists' drug selection skills. Concurrently, academic programs should be provided to increase the clinical skills of both practitioners and students still in training.

## REFERENCES


1. Doering PL, McCormick WC, Klapp DL et al. Therapeutic substitution and the hospital formulary system. Am J Hosp Pharm. 1982; 38:1949-51.
2. Hager T. Drawing the battle lines. Pharm Exec. Aug 82:58-61.
3. Doering PL, McCormick WC, Klapp DL et al. State regulatory positions concerning therapeutic substitutions in hospitals. Am J Hosp Pharm. 1982; 38:1900-3.
4. Doering PL, McCormick WC, Klapp DL et al. Therapeutic substitution practices in short-term hospitals. Am J Hosp Pharm. 1982; 38;1028-32.
5. White JP. Prescribe? PD? Just let me show my stuff. Drug Topics. 1983; 1983;51.
6. American Pharmacy. 1984; 2:12.
7. Dillman DA. Main and telephone surveys--the total design method. Wiley-Interscience, New York, New York.

Table 1. Sex And Age Distribution Of Respondents.

| Demographic Characteristic | Physicians | | Pharmacists | |
|---|---|---|---|---|
| | No. | Rel. % | No. | Rel. % |
| **Sex** | | | | |
| Female | 12 | 23 | 24 | 24 |
| Male | 40 | 77 | 80 | 76 |
| **Age** | | | | |
| 24-35 | 23 | 46 | 24 | 25 |
| 36-45 | 11 | 22 | 31 | 32 |
| 46-55 | 5 | 10 | 15 | 16 |
| 56-65 | 8 | 16 | 17 | 18 |
| Over 65 | 3 | 6 | 9 | 9 |

Table 2. Part A. Physician Distribution By Specialty.

| | No. | Relative % |
|---|---|---|
| Family Practice | 14 | 27 |
| Internal Medicine | 10 | 20 |
| Pediatrics | 9 | 17 |
| Surgery | 4 | 8 |
| Ob-Gyn | 4 | 8 |
| Other | 10 | 20 |

Part B. Pharmacist Distribution By Degree.

| | No. | Relative % |
|---|---|---|
| Bachelor of Science | 73 | 78 |
| Graduate Degree | 13 | 14 |
| Other | 8 | 8 |

Table 3. Mean Attitudinal Responses To Statements Regarding The Appropriateness Of Therapeutic Alternate Substitution (TAS) and Pharmaceutical Alternate Substitution (PAS) In Hospitals and Community Pharmacies.

| | TAS | | PAS | |
|---|---|---|---|---|
| | MD Mean (SD) | RPh | MD Mean (SD) | RPh |
| **In Hospitals** | | | | |
| Drugs Selected Using RPh & MD Mutually Agreed Upon Protocols | 3.56 (1.28) | 4.24* (0.85) | 3.44 (1.14) | 3.42 (1.30) |
| If RPh Informs MD of Change | 3.20 (1.34) | 3.70* (1.19) | 3.77 (1.08) | 3.96 (1.09) |
| If Medical Staff Committee Selects Alternates | 3.29 (1.26) | 4.10* (1.05) | 3.80 (1.05) | 4.00 (1.13) |
| Without Prior MD Consent | 1.40 (0.85) | 2.28* (1.36) | 2.20 (1.11) | 3.12* (1.46) |
| **In Community Pharmacies** | | | | |
| Drugs Selected Using RPh & MD Mutually Agreed Upon Protocols | 3.07 (1.37) | 4.04* (0.97) | 3.30 (1.14) | 3.41 (1.32) |
| If RPh Informs MD Of Change | 3.02 (1.35) | 3.76* (1.27) | 3.54 (1.14) | 3.83 (1.16) |
| Without Prior MD Consent | 1.30 (0.63) | 2.13* (1.32) | 1.94 (1.04) | 2.87* (1.47) |

1=Strongly Disagree, 2=Disagree, 3=No Opinion, 4=Agree, 5=Strongly Agree
*=difference significant at .05 level

Table 4. Mean Responses To The Attitudinal Statements Following The Statements Permitting Pharmacists To Select Therapeutic Alternates (TAs) and Pharmaceutical Alternates (PAs).

| | TAs | | PAs | |
|---|---|---|---|---|
| | MD Mean | RPh (SD) | MD Mean | RPh (SD) |
| May Contribute To Lower Rx Prices To To Consumers | 3.20 (1.15) | 3.80* (1.17) | 3.34 (0.97) | 3.95* (1.08) |
| May Help To Increase Patient Compliance | 2.42 (0.87) | 3.24* (1.24) | 2.71 (1.11) | 3.46* (1.21) |
| Would Be Acceptable If RPh Has Completed Appropriate Certified CE Courses | 2.46 (1.06) | 3.31* (1.23) | 2.94 (1.01) | 3.34* (1.13) |
| Would Be Acceptable If The Patient Agreed To The Change | 2.33 (1.10) | 3.16* (1.22) | 2.78 (1.10) | 3.46* (1.15) |
| Would Increase The Frequency Of Inappropriate Drug Therapy If Practiced In: | | | | |
| Hospitals | 2.77 (0.89) | 2.37* (1.14) | 2.75 (0.94) | 2.01* (0.98) |
| Community Pharmacies | 3.16 (1.01) | 2.60* (1.22) | 2.95 (0.97) | 2.06* (0.99) |
| Would Be Acceptable In Sites Where RPh Has Access To Patient Medical Records | 2.15 (0.97) | 3.55* (1.17) | 2.60 (1.12) | 3.39* (1.18) |

---

1=Strongly Disagree, 2=Disagree, 3=No Opinion, 4=Agree, 5=Strongly Agree
*=significant at .05 level

Table 5. Means Responses To Attitudinal Statements Concerning Other Identified Issues With Therapeutic Alternate Substitution (TAS) and Pharmaceutical Alternate Substitution (PAS).

| | TAS | | PAS | |
|---|---|---|---|---|
| | MD Mean | RPh (SD) | MD Mean | RPh (SD) |
| A Conflict of Interest Exists When A Physician Routinely Dispenses Medication | 2.73 (1.17) | 4.17* (1.02) | | |
| A Conflict of Interest Would Exist If Pharmacists Were Allowed To Unilaterally Select And Dispense Medications | 4.05 (0.86) | 3.10* (1.35) | 3.57 (0.93) | 2.66* (1.23) |
| Community Pharmacists Have Sufficient Knowledge Of The Therapeutic Properties Of Drugs To Make Rational Substitutions | 2.47 (0.96) | 3.53* (1.14) | 3.24 (0.96) | 4.02* (0.84) |
| Hospital Pharmacists | 2.80 (1.10) | 3.84* (1.04) | | |
| There Are Drug Classes Which Contain Drug Products With No Therapeutic Advantages Over Each Other | 3.45 (0.89) | 3.53 (1.13) | | |
| The TAS/PAS Issue Could Weaken The Relationship Between Medicine And Pharmacy | 3.18 (0.92) | 3.01 (1.26) | 2.98 (1.09) | 2.43* (1.20) |
| Your Training/Experience Has Provided You With Skills To Make Rational Selections | | 3.95 (0.99) | | 4.16 (0.85) |

1=Strongly Disagree, 2=Disagree, 3=No Opinion, 4=Agree, 5=Strongly Agree
*=significant at .05 level

Table 6. Cumulative Responses To The Question Regarding Whether Or Not The Respondent Currently Favors Regulations Allowing Therapeutic Alternate Substitution (TAS) And Pharmaceutical Alternate Substitution (PAS).

| | TAS | | | |
|---|---|---|---|---|
| | MD | Rel % | RPh | Rel % |
| Yes, With Restrictions | 26 | 46% | 69 | 67% |
| Yes | 0 | 0% | 14 | 14% |
| No | 28 | 50% | 17 | 17% |
| Don't Know | 2 | 4% | 2 | 2% |
| | PAS | | | |
| Yes, With Restrictions | 31 | 55% | 46 | 46% |
| Yes | 4 | 7% | 48 | 48% |
| No | 21 | 38% | 6 | 6% |
| Don't Know | 0 | | 0 | |

Table 7. Cumulative Responses Regarding Conditions Under Which Therapeutic Alternate Substitution (TAS) and Pharmaceutical Alternate Substitution (PAS) Would Be Approved.

| | TAS | | PAS | |
|---|---|---|---|---|
| | MD | RPh | MD | RPh |
| If Substitutions Are Made According To RPh & MD Mutually Agreed Upon Protocols | 19 | 49 | 22 | 28 |
| If Alternates Are Selected By A Pharmacy & Therapeutics Committee | 13 | 39 | 16 | 24 |
| If The RPh Informs The MD Of The Change | 10 | 30 | 16 | 21 |
| If The Substitution Would Save The Patient Money | 4 | 9 | 6 | 8 |
| Other | 0 | 0 | 0 | 6 |

Table 8. Cumulative Responses Regarding The Best Reasons For Passing Regulations Allowing Pharmacists To Select Therapeutic Alternates (TAs) and Pharmaceutical Alternates (PAs).

| | TAs | | PAs | |
|---|---|---|---|---|
| | MD | RPh | MD | RPh |
| Would Result In Lower RX Prices To Consumers | 18 | 48 | 24 | 41 |
| Would Promote More Rational Drug Therapy | 11 | 36 | 12 | 25 |
| Would Allow Society To More Fully Utilize The RPh's Training And Expertise | 8 | 43 | 9 | 45 |
| The RPh Is Knowledgeable Enough To Select Alternate Drugs | 5 | 18 | 17 | 30 |
| Other | 4 | 7 | 0 | 22* |

*Would Increase Patient Compliance

Table 9. Cumulative Responses Regarding The Information The Pharmacist Needs To Have Before Selecting An Alternate Drug.

| | TA | | PA | |
|---|---|---|---|---|
| | MD | RPh | MD | RPh |
| Therapeutic Equivalence Data | 21 | 70 | | |
| Costs Of Alternative Drug Therapy | 21 | 44 | 29 | 55 |
| Patient's Drug Allergies | 19 | 60 | 22 | 49 |
| Patient's Diagnosis | 16 | 64 | 19 | 39 |
| Bioequivalence Data | | | 29 | 85 |
| Other | 9 | 11 | 7 | 11 |

Table 10. Cumulative Responses Regarding Best Reasons For Not Passing Regulations Allowing Pharmacists To Select Therapeutic Alternates (TAs) and Pharmaceutical Alternates (PAs).

| | TAs | | PAs | |
|---|---|---|---|---|
| | MD | RPh | MD | RPh |
| MD Is More Familiar With The Patient's Condition And Therefore Better Informed As To The Patient's Needs | 25 | 16 | 18 | 5 |
| Drug Selection Is Solely The MD's Responsibility | 13 | 7 | 5 | 3 |
| MD Is The Only Member Of The Health Care Team Qualified To Select Alternates | 3 | 1 | 3 | 1 |
| Other | 10* | 1 | 10* | 1 |

*Increased Liability Most Frequent Response

Appendix A. Physician Questionnaire.

The purpose of this questionnaire is to obtain your attitudes towards pharmacists selecting a THERAPEUTIC or PHARMACEUTICAL ALTERNATE drug on a prescription. Various pharmaceutical associations and several state boards of pharmacy are presently wrestling with the problem of establishing policy or regulations in this area. The results of this survey should provide information and data to assist policy makers in their decision making process. All replies to this questionnaire will remain confidential and only summary data will be reported. The number on the questionnaire is for the sole purpose of keeping track of responses.

The questionnaire consists of 32 questions which can be answered by either circling a response or providing a short written statement. If you would like to provide written comments, there is room at the end of the questionnaire. It will take approximately 10 minutes to complete this questionnaire. If you have any questions please call us at 919-962-0076. Thank you for taking the time to complete the questionnaire.

Sincerely,

Roger Wetherington, B.Sc.
M.Sc. Candidate
University of North Carolina
Chapel Hill, NC 27514

Jean Paul Gagnon, Ph.D.
University of North Carolina
Chapel Hill, NC 27514

_____ No.

SECTION I: To answer the following questions, you must understand the definition of THERAPEUTIC ALTERNATES given below. Please read it carefully and proceed to the questions when you feel you understand the definition.

THERAPEUTIC ALTERNATES: Drug products containing different therapeutic moieties but which are of the same pharmacologic and/or therapeutic class and which can be expected to have similar therapeutic effects when administered to patients in therapeutically equivalent doses. For example, prednisone and prednisolone; or ampicillin and amoxicillin.

| PLEASE CIRCLE THE RESPONSE TO THE RIGHT OF EACH STATEMENT WHICH INDICATES YOUR LEVEL OF AGREEMENT | Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree |
|---|---|---|---|---|---|
| 1. Permitting pharmacists to select THERAPEUTIC ALTERNATES for prescribed drugs is appropriate: | | | | | |
| A. in HOSPITALS and other INSTITUTIONAL sites: | | | | | |
| if the drugs are selected using pharmacist and physician mutually agreed upon protocols; | A | B | C | D | E |
| if the pharmacist informs the physician of the change; | A | B | C | D | E |
| if the drugs are selected by a committee of the medical staff such as a hospital Pharmacy and Therapeutics Committee; | A | B | C | D | E |
| without the physician's prior consent; | A | B | C | D | E |
| B. in COMMUNITY PHARMACIES | | | | | |
| if the drugs are selected using pharmacist and physician mutually agreed upon protocols; | A | B | C | D | E |
| if the pharmacist informs the physician of the change; | A | B | C | D | E |
| without the physician's prior consent; | A | B | C | D | E |

| PLEASE CIRCLE THE RESPONSE TO THE RIGHT OF EACH STATEMENT WHICH INDICATES YOUR LEVEL OF AGREEMENT | Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree |
|---|---|---|---|---|---|
| 2. Permitting pharmacists to select THERAPEUTIC ALTERNATES: | | | | | |
| may contribute to lowering prescription prices to consumers; | A | B | C | D | E |
| may help to increase patient compliance; | A | B | C | D | E |
| would be acceptable if the pharmacist has completed appropriate certified CE courses; | A | B | C | D | E |
| would be acceptable if the patient agreed to the change; | A | B | C | D | E |
| would increase the frequency of inappropriate drug therapy if practiced in HOSPITALS and/or other INSTITUTIONAL sites; | A | B | C | D | E |
| would increase the frequency of inappropriate drug therapy if practiced in COMMUNITY PHARMACIES; | A | B | C | D | E |
| would be acceptable in practice sites where the pharmacist has access to patient medical records. | A | B | C | D | E |
| 3. A conflict of interest exists when a physician routinely dispenses medication to his/her patients. | A | B | C | D | E |
| 4. COMMUNITY PHARMACISTS have sufficient knowledge of the therapeutic properties of drugs to make rational THERAPEUTIC ALTERNATE selections. | A | B | C | D | E |
| 5. HOSPITAL PHARMACISTS have sufficient knowledge of the therapeutic properties of drugs to make rational THERAPEUTIC ALTERNATE selections. | A | B | C | D | E |
| 6. A conflict of interest would exist if pharmacists were allowed to unilaterally select and dispense THERAPEUTIC ALTERNATES. | A | B | C | D | E |
| 7. There are drug classes, e.g. thiazides, which contain drug products with no therapeutic advantages over each other. | A | B | C | D | E |
| 8. The THERAPEUTIC ALTERNATE selection issue could weaken the relationship between medicine and pharmacy. | A | B | C | D | E |

PLEASE CIRCLE THE APPROPRIATE RESPONSE.

9. At the present time, are you in favor of regulations ALLOWING the selection of THERAPEUTIC ALTERNATE drugs by pharmacists?

   1. Yes, with restrictions (PLEASE GO TO QUESTION #10)
   2. Yes (PLEASE GO TO QUESTION #11)
   3. No (PLEASE GO TO QUESTION #13)
   4. Don't know (PLEASE GO TO QUESTION #14)

10. Please indicate TWO conditions under which you would approve selection of a THERAPEUTIC ALTERNATE drug.

    1. If the therapeutic alternate drugs are selected by a Pharmacy and Therapeutics Committee
    2. If the pharmacist informs the physician that a substitution is being made
    3. If the substitutions are made according to mutually agreed upon protocols between individual pharmacists and physicians
    4. If on a prescription costing $10.00, selection of a therapeutic alternate drug would save the patient: (please circle one figure)

       1. $1.00 2. $2.50 3. $4.00

    5. Other (please specify) _____
       _____

11. Please select the TWO BEST reasons for PASSING regulations allowing the selection of THERAPEUTIC ALTERNATE drugs by pharmacists.

    1. Would result in lower prescription prices to consumers
    2. Would promote more rational drug therapy
    3. The pharmacist is knowledgeable enough to select therapeutic alternate drugs
    4. Would allow society to more fully utilize the training and expertise of the pharmacist
    5. Other (please specify) _____
       _____

12. What information must a pharmacist have before selecting a THERAPEUTIC ALTERNATE drug? (may choose more than one)

    1. Patient's diagnosis
    2. Patient's drug allergies
    3. Therapeutic equivalence drug data
    4. Cost of alternative drug therapy
    5. Other (please specify) _____
       _____

PLEASE SKIP TO THE BEGINNING OF SECTION II AND CONTINUE.

13. Please select the TWO BEST reasons for NOT PASSING regulations allowing the selection of THERAPEUTIC ALTERNATE drugs by pharmacists.

1. The doctor is more familiar with the patient's condition and therefore better informed as to the patient's needs.
2. The legal liability for physicians would be increased.
3. Drug selection is solely the physician's responsibility.
4. The physician is the only member of the health care team qualified to select a therapeutic alternate drug.
5. Other (please specify) _____

_____

PLEASE SKIP TO BEGINNING OF SECTION II AND CONTINUE.

14. What information would you need to make a decision regarding the establishment of policy or regulations concerning pharmacist selection of therapeutic alternates? _____

_____

_____

SECTION II: To answer the following questions, you must understand the definition of PHARMACEUTICAL ALTERNATES given below. Please read it carefully and proceed to the questions when you feel you understand the definition.

PHARMACEUTICAL ALTERNATES: Drug products which contain the same therapeutic moiety but differ in the salt or ester of the moiety (tetracycline HCl and tetracycline phosphate capsules) or in the dosage form (ampicillin capsules and ampicillin suspension) and use the same route of administration.

| PLEASE CIRCLE THE RESPONSE TO THE RIGHT OF EACH STATEMENT WHICH INDICATES YOUR LEVEL OF AGREEMENT | Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree |
|---|---|---|---|---|---|
| 15. Permitting pharmacists to select PHARMACEUTICAL ALTERNATES is apropriate: | | | | | |
| A. in HOSPITALS and other INSTITUTIONAL sites: | | | | | |
| if the pharmacist informs the physician of the change; | A | B | C | D | E |
| if the drugs are selected using pharmacist and physician mutually agreed upon protocols; | A | B | C | D | E |
| if the drugs are screened and selected by a committee of the medical staff, such as a hospital Pharmacy and Therapeutics Committee; | A | B | C | D | E |
| without the physician's prior consent | A | B | C | D | E |
| B. In COMMUNITY PHARMACIES | | | | | |
| if the pharmacist informs the physician of the change; | A | B | C | D | E |
| if the drugs are selected using pharmacist and physician mutually agreed upon protocols; | A | B | C | D | E |
| without the physician's prior consent. | A | B | C | D | E |

| PLEASE CIRCLE THE RESPONSE TO THE RIGHT OF EACH STATEMENT WHICH INDICATES YOUR LEVEL OF AGREEMENT | Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree |
|---|---|---|---|---|---|
| 16. Permitting pharmacists to select PHARMACEUTICAL ALTERNATES: | | | | | |
| may contribute to lowering prescription prices to consumers; | A | B | C | D | E |
| may help to increase patient compliance; | A | B | C | D | E |
| would be acceptable if the pharmacist has completed appropriate certified CE courses; | A | B | C | D | E |
| would be acceptable if the patient agreed to the changes; | A | B | C | D | E |
| would increase the frequency of inappropriate drug therapy if practiced in HOSPITALS and/or other INSTITUTIONAL sites; | A | B | C | D | E |
| would increase the frequency of inappropriate drug therapy if practiced in COMMUNITY pharmacies: | A | B | C | D | E |
| would be acceptable in practice sites where the pharmacist has access to the patient's medical record. | A | B | C | D | E |
| 17. A conflict of interest would exist if pharmacists were allowed to unilaterally select and dispense PHARMACEUTICAL ALTERNATES. | A | B | C | D | E |
| 18. Community pharmacists have sufficient knowledge of the therapeutic properties of drugs to make rational PHARMACEUTICAL ALTERNATE selections. | A | B | C | D | E |
| 19. The issue of PHARMACEUTICAL ALTERNATE selection could weaken the relationship between pharmacy and medicine. | A | B | C | D | E |

PLEASE CIRCLE THE APPROPRIATE RESPONSE.

20. At the present time, are you in favor of regulations allowing the selection of PHARMACEUTICAL ALTERNATES by pharmacists?

    1. Yes, with restrictions (PLEASE GO TO QUESTION #21)
    2. Yes (PLEASE GO TO QUESTION #22)
    3. No (PLEASE GO TO QUESTION #24)
    4. Don't know (PLEASE GO TO QUESTION #25)

21. Please indicate TWO conditions under which you would approve selection of PHARMACEUTICAL ALTERNATES.

    1. If the pharmaceutical alternates are selected by a Pharmacy and Therapeutics Committee
    2. If the pharmacist informs the physician that a substitution is being made
    3. If the substitutions are made according to mutually agreed upon protocols between individual pharmacists and physicians
    4. If on a prescription costing $10.00, substituting a pharmaceutical alternate would save the patient: (please circle one figure)

       1. $1.00 2. $2.50 3. $4.00

    5. Other (please specify) _____
       _____

22. Please select the TWO BEST reasons for PASSING regulations allowing the selection of PHARMACEUTICAL ALTERNATES.

    1. Would result in lower prescription prices to consumers
    2. Would promote more rational drug use
    3. The pharmacist is knowledgeable enough to select pharmaceutical alternates
    4. Would allow society to more fully benefit from the training and expertise of the pharmacist
    5. Would increase patient compliance
    6. Other (please specify) _____
       _____

23. What information must a pharmacist have before selecting a PHARMACEUTICAL ALTERNATE? (may choose more than one)

    1. Patient's diagnosis
    2. Patient's drug allergies
    3. Bioequivalence data
    4. Cost of alternative drug therapy
    5. Other (please specify) _____
       _____

PLEASE SKIP TO QUESTION #26 AND CONTINUE.

24. Please select the TWO BEST reasons for NOT PASSING regulations allowing selection of PHARMACEUTICAL ALTERNATES.

1. The doctor is more familiar with the patient's condition and therefore better informed as to the patient's needs.
2. The legal liability for physicians would be increased.
3. Drug selection is solely the physician's responsibility.
4. The physician is the only member of the health care team qualified to select pharmaceutical alternates.
5. Other (please specify) _____

_____

PLEASE SKIP TO QUESTION #26 AND CONTINUE.

25. What information is needed to make a decision regarding the establishment of policy or regulations concerning pharmacist selection of pharmaceutical alternates? _____

_____

_____

26. Years in practice _____ 27. Age _____ 28. Sex ___F ___M

29. State in which you practice _____

30. Year graduated from medical school _____

31. Please indicate your area(s) of specialty.

| | |
|---|---|
| _____ Family practice | _____ Internal medicine |
| _____ Dermatology | _____ Surgery |
| _____ Neurology | _____ Ob-Gyn |
| _____ Urology | _____ Orthopedics |
| _____ Pediatrics | _____ Ophthalmology |
| _____ Psychology | _____ Other (please specify) |
| | _____ |

32. Please indicate the approximate percentage of your time spent in each practice area.

_____% Hospital inpatient care
_____% Hospital clinic ambulatory care
_____% Private ambulatory care
_____% Teaching
_____% State or federal hospital
_____% Other (please specify) _____

Total 100%

The following space is provided for any additional comments you may wish to add. Please do not hesitate to add your opinions or insights.

You have completed this questionnaire. Please fold over the inside page so that our return address shows. Staple or tape the cover shut and mail the questionnaire back to us. Postage has been attached. Thank you very much for your help.

Appendix B. Pharmacist Questionnaire.

The purpose of this questionnaire is to obtain your attitudes towards pharmacists selecting a THERAPEUTIC or PHARMACEUTICAL ALTERNATE drug on a prescription. Various pharmaceutical associations and several state boards of pharmacy are presently wrestling with the problem of establishing policy or regulations in this area. The results of this survey should provide information and data to assist policy makers in their decision making process. All replies to this questionnaire will remain confidential and only summary data will be reported. The number on the questionnaire is for the sole purpose of keeping track of responses.

The questionnaire consists of 39 questions which can be answered by either circling a response or providing a short written statement. If you would like to provide written comments, there is room at the end of the questionnaire. It will take approximately 10 minutes to complete this questionnaire. If you have any questions please call us at 919-962-0076. Thank you for taking the time to complete the questionnaire.

Sincerely,

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SECTION I: To answer the following questions, you must understand the definition of THERAPEUTIC ALTERNATES given below. Please read it carefully and proceed to the questions when you feel you understand the definition.

THERAPEUTIC ALTERNATES: Drug products containing different therapeutic moieties but which are of the same pharmacologic and/or therapeutic class and which can be expected to have similar therapeutic effects when administered to patients in therapeutically equivalent doses. For example, prednisone and prednisolone; or ampicillin and amoxicillin.

| PLEASE CIRCLE THE RESPONSE TO THE RIGHT OF EACH STATEMENT WHICH INDICATES YOUR LEVEL OF AGREEMENT | Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree |
|---|---|---|---|---|---|
| 1. Permitting pharmacists to select THERAPEUTIC ALTERNATES for prescribed drugs is appropriate: | | | | | |
| A. in HOSPITALS and other INSTITUTIONAL sites: | | | | | |
| if the drugs are selected using pharmacists and physician mutually agreed upon protocols; | A | B | C | D | E |
| if the pharmacist informs the physician of the change; | A | B | C | D | E |
| if the drugs are selected by a committee of the medical staff such as a hospital Pharmacy and Therapeutics Committee; | A | B | C | D | E |
| without the physician's prior consent; | A | B | C | D | E |
| B. in COMMUNITY PHARMACIES | | | | | |
| if the drugs are selected using pharmacist and physician mutually agreed upon protocols; | A | B | C | D | E |
| if the pharmacist informs the physician of the change; | A | B | C | D | E |
| without the physician's prior consent; | A | B | C | D | E |

| PLEASE CIRCLE THE RESPONSE TO THE RIGHT OF EACH STATEMENT WHICH INDICATES YOUR LEVEL OF AGREEMENT | Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree |
|---|---|---|---|---|---|
| 2. Permitting pharmacists to select THERAPEUTIC ALTERNATES: | | | | | |
| may contribute to lowering prescription prices to consumers; | A | B | C | D | E |
| may help to increase patient conpliance; | A | B | C | D | E |
| would be acceptable if the pharmacist has completed appropriate certified CE courses; | A | B | C | D | E |
| would be acceptable if the patient agreed to the change; | A | B | C | D | E |
| would increase the frequency of inappropriate drug therapy if practiced in HOSPITALS and/or other INSTITUTIONAL sites; | A | B | C | D | E |
| would increase the frequency of inappropriate drug therapy if practiced in COMMUNITY PHARMACIES; | A | B | C | D | E |
| would be acceptable in practice sites where the pharmacist has access to patient medical records. | A | B | C | D | E |
| 3. A conflict of interest exists when a physician routinely dispenses medication to his/her patients. | A | B | C | D | E |
| 4. COMMUNITY PHARMACISTS have sufficient knowledge of the therapeutic properties of drugs to make rational THERAPEUTIC ALTERNATE selections. | A | B | C | D | E |
| 5. HOSPITAL PHARMACISTS have sufficient knowledge of the therapeutic properties of drugs to make rational THERAPEUTIC ALTERNATE selections. | A | B | C | D | E |
| 6. A conflict of interest would exist if pharmacists were allowed to unilaterally select and dispense THERAPEUTIC ALTERNATES. | A | B | C | D | E |
| 7. There are drug classes, e.g. thiazides, which contain drug products with no therapeutic advantages over each other. | A | B | C | D | E |

| PLEASE CIRCLE THE RESPONSE TO THE RIGHT OF EACH STATEMENT WHICH INDICATES YOUR LEVEL OF AGREEMENT | Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree |
|---|---|---|---|---|---|
| 8. The THERAPEUTIC ALTERNATE selection issue could weaken the relationship between medicine and pharmacy. | A | B | C | D | E |
| 9. Selecting THERAPEUTIC ALTERNATE drugs will increase the legal liability of pharmacists. | A | B | C | D | E |
| 10. Your training and/or experience have provided you with the skills necessary to make rational THERAPEUTIC ALTERNATE selections. | A | B | C | D | E |

PLEASE CIRCLE THE APPROPRIATE RESPONSE.

11. At the present time, are you in favor of regulations ALLOWING the selection of THERAPEUTIC ALTERNATE drugs by pharmacists?

    1. Yes, with restrictions (PLEASE GO TO QUESTION #12)
    2. Yes (PLEASE GO TO QUESTION #13)
    3. No (PLEASE GO TO QUESTION #15)
    4. Don't know (PLEASE GO TO QUESTION #16)

12. Please indicate TWO conditions under which you would approve selection of a THERAPEUTIC ALTERNATE drug.

    1. If the therapeutic alternate drugs are selected by a Pharmacy and Therapeutics Committee
    2. If the pharmacist informs the physician that a substitution is being made
    3. If the substitutions are made according to mutually agreed upon protocols between individual pharmacists and physicians
    4. If on a prescription costing $10.00, selection of a therapeutic alternate drug would save the patient: (please circle one figure)

       1. $1.00 2. $2.50 3. $4.00

    5. Other (please specify) _____

13. Please select the TWO BEST reasons for PASSING regulations allowing the selection of THERAPEUTIC ALTERNATE drugs by pharmacists.

1. Would result in lower prescription prices to consumers
2. Would promote more rational drug therapy
3. The pharmacist is knowledgeable enough to select therapeutic alternate drugs
4. Would allow society to more fully utilize the training and expertise of the pharmacist
5. Other (please specify) _____

_____

14. What information must a pharmacist have before selecting a THERAPEUTIC ALTERNATE drug? (may choose more than one)

1. Patient's diagnosis
2. Patient's drug allergies
3. Therapeutic equivalence drug data
4. Cost of alternative drug therapy
5. Other (please specify) _____

_____

PLEASE SKIP TO THE BEGINNING OF SECTION II AND CONTINUE.

15. Please select the TWO BEST reasons for NOT PASSING regulations allowing the selection of THERAPEUTIC ALTERNATE drugs by pharmacists.

1. The doctor is more familiar with the patient's condition and therefore better informed as to the patient's needs.
2. The legal liability for physicians would be increased.
3. Drug selection is solely the physician's responsibility.
4. The physician is the only member of the health care team qualified to select a therapeutic alternate drug.
5. Other (please specify) _____

_____

PLEASE SKIP TO BEGINNING OF SECTION II AND CONTINUE.

16. What information would you need to make a decision regarding the establishment of policy or regulations concerning pharmacist selection of therapeutic alternates? _____

_____

_____

SECTION II: To answer the following questions, you must understand the definition of PHARMACEUTICAL ALTERNATES given below. Please read it carefully and proceed to the questions when you feel you understand the definition.

PHARMACEUTICAL ALTERNATES: Drug products which contain the same therapeutic moiety but differ in the salt or ester of the moiety (tetracycline HCl and tetracycline phosphate capsules) or in the dosage form (ampicillin capsules and ampicillin suspension) and use the same route of administration.

| PLEASE CIRCLE THE RESPONSE TO THE RIGHT OF EACH STATEMENT WHICH INDICATES YOUR LEVEL OF AGREEMENT | Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree |
|---|---|---|---|---|---|
| 17. Permitting pharmacists to select PHARMACEUTICAL ALTERNATES is apropriate: | | | | | |
| A. in HOSPITALS and other INSTITUTIONAL sites: | | | | | |
| if the pharmacist informs the physician of the change; | A | B | C | D | E |
| if the drugs are selected using pharmacist and physician mutually agreed upon protocols; | A | B | C | D | E |
| if the drugs are screened and selected by a committee of the medical staff, such as a hospital Pharmacy and Therapeutics Committee; | A | B | C | D | E |
| without the physician's prior consent | A | B | C | D | E |
| B. In COMMUNITY PHARMACIES | | | | | |
| if the pharmacist informs the physician of the change; | A | B | C | D | E |
| if the drugs are selected using pharmacist and physician mutually agreed upon protocols; | A | B | C | D | E |
| without the physician's prior consent. | A | B | C | D | E |

| PLEASE CIRCLE THE RESPONSE TO THE RIGHT OF EACH STATEMENT WHICH INDICATES YOUR LEVEL OF AGREEMENT | Strongly Agree | Agree | No Opinion | Disagree | Strongly Disagree |
|---|---|---|---|---|---|
| 18. Permitting pharmacists to select PHARMACEUTICAL ALTERNATES: | | | | | |
| may contribute to lowering prescription prices to consumers; | A | B | C | D | E |
| may help to increase patient compliance; | A | B | C | D | E |
| would be acceptable if the pharmacist has completed appropriate certified CE courses; | A | B | C | D | E |
| would be acceptable if the patient agreed to the changes; | A | B | C | D | E |
| would increase the frequency of inappropriate drug therapy if practiced in HOSPITALS and/or other INSTITUTIONAL sites; | A | B | C | D | E |
| would increase the frequency of inappropriate drug therapy if practiced in COMMUNITY pharmacies; | A | B | C | D | E |
| would be acceptable in practice sites where the pharmacist has access to the patient's medical record. | A | B | C | D | E |
| 19. A conflict of interest would exist if pharmacists were allowed to unilaterally select and dispense PHARMACEUTICAL ALTERNATES. | A | B | C | D | E |
| 20. Community pharmacists have sufficient knowledge of the therapeutic properties of drugs to make rational PHARMACEUTICAL ALTERNATE selections. | A | B | C | D | E |
| 21. The issue of PHARMACEUTICAL ALTERNATE selection could weaken the relationship between pharmacy and medicine. | A | B | C | D | E |
| 22. Selection of PHARMACEUTICAL ALTERNATES will increase the legal liability of pharmacists. | A | B | C | D | E |
| 23. Your training and/or experience have provided you with the skills necessary to make rational THERAPEUTIC ALTERNATE selections. | A | B | C | D | E |

PLEASE CIRCLE THE APPROPRIATE RESPONSE.

24. At the present time, are you in favor of regulations allowing the selection of PHARMACEUTICAL ALTERNATES by pharmacists?

    1. Yes, with restrictions (PLEASE GO TO QUESTION #25)
    2. Yes (PLEASE GO TO QUESTION #26)
    3. No (PLEASE GO TO QUESTION #28)
    4. Don't know (PLEASE GO TO QUESTION #29)

25. Please indicate TWO conditions under which you would approve selection of PHARMACEUTICAL ALTERNATES.

    1. If the pharmaceutical alternates are selected by a Pharmacy and Therapeutics Committee
    2. If the pharmacist informs the physician that a substitution is being made
    3. If the substitutions are made according to mutually agreed upon protocols between individual pharmacists and physicians
    4. If on a prescription costing $10.00, substituting a pharmaceutical alternate would save the patient: (please circle one figure)

       1. $1.00 2. $2.50 3. $4.00

    5. Other (please specify) _____
       _____

26. Please select the TWO BEST reasons for PASSING regulations allowing the selection of PHARMACEUTICAL ALTERNATES.

    1. Would result in lower prescription prices to consumers
    2. Would promote more rational drug therapy
    3. The pharmacist is knowledgeable enough to select pharmaceutical alternates
    4. Would allow society to more fully benefit from the training and expertise of the pharmacist
    5. Would increase patient compliance
    6. Other (please specify) _____
       _____

27. What information must a pharmacist have before selecting a PHARMACEUTICAL ALTERNATE? (may choose more than one)

    1. Patient's diagnosis
    2. Patient's drug allergies
    3. Bioequivalence data
    4. Cost of alternative drug therapy
    5. Other (please specify) _____
       _____

PLEASE SKIP TO QUESTION #30 AND CONTINUE.

28. Please select the TWO BEST reasons for NOT PASSING regulations allowing selection of PHARMACEUTICAL ALTERNATES.

1. The doctor is more familiar with the patient's condition and therefore better informed as to the patient's needs.
2. The legal liability for physicians would be increased.
3. Drug selection is solely the physician's responsibility.
4. The physician is the only member of the health care team qualified to select pharmaceutical alternates.
5. Other (please specify) _____

_____

PLEASE SKIP TO QUESTION #30 AND CONTINUE.

29. What information is needed to make a decision regarding the establishment of policy or regulations concerning pharmacist selection of pharmaceutical alternates?_____

_____

_____

30. Approximately how many times in the past month have you SUBSTITUTED a PHARMACEUTICAL ALTERNATE or THERAPEUTIC ALTERNATE on a prescription?

_____ 1. PHARMACEUTICAL ALTERNATE
_____ 2. THERAPEUTIC ALTERNATE

31. To what extent do you substitute generic drugs on prescriptions for multisource drugs at the present time?

1. 0%
2. Less than 25%
3. Greater than 25%, but less than or equal to 50%
4. Greater than 50%, but less than or equal to 75%
5. Greater than 75%

32. Do you think that the potential increased liability for pharmacists is a valid reason for rejecting selection of THERAPEUTIC ALTERNATES and PHARMACEUTICAL ALTERNATES as a pharmacist function?

1. Yes
2. No

33. In what state do you practice? _____

34. Your age (yrs) _____ 35. Your sex _____

36. Years in practice _____

37. Year gradauted from pharmacy school _____

38. Highest degree you hold:

1. B Sc Ph
2. PharmD
3. M Sc Ph
4. Ph D
5. Other (please specify) _____

39. Please indicate the approximate percentage of your time spent in each practice area.

_____% Independent community practice
_____% Hospital or other institutional setting
_____% Small chain (10 or less stores)
_____% Large chain (greater than 10 stores)
_____% State or federal hospital
_____% Teaching
_____% Other (please specify) _____

Total 100%

The following space is provided for any additional comments you may wish to add. Please do not hesitate to add your opinions or insights.

You have completed this questionnaire. Please fold over the inside page so that our return address shows. Staple or tape the cover shut and mail the questionnaire back to us. Postage has been attached. Thank you very much for your help.